Additional File 4: Informed Consent Form for FHS

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

STUDY INFORMATION

Protocol Title:

The Effect of **Fert**ility Health Awareness **Stra**tegies on Fe**rt**ility Knowledge and Childbearing in Young Married Couples (FertStart)

Principal Investigator:

A/Prof Yu Su Ling
Department of Obstetrics & Gynecology
Singapore General Hospital (SGH)
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Tel: 6576 7743

Site Principal Investigator:

Dr Chua Ka Hee
Department of Reproductive Medicine
KK Women's and Children's Hospital (KKH)
100 Bukit Timah Road
Singapore 229899
Tel: 9822 7616

Sponsor:

Strategy Group, Prime Minister's Office (PMO)

PURPOSE OF THE RESEARCH STUDY

Before you take part in this research study, the study must be explained to you and you must be given the chance to ask questions. Please read carefully the information provided here. If you agree to participate, please sign the consent form. You will be given a copy of this document to take home with you.

The purpose of this study is to study the effect of fertility health screening and fertility awareness tools on parenthood intentions, as well as fertility awareness, conception efforts and births among young married couples. We hope to learn which method of providing fertility education and modifying childbearing beliefs is more effective. This study will recruit 1200 couples from the community.

You had earlier given your verbal consent to participate in the study and you were assigned to the fertility screening group. **As part of the study, we are seeking your written consent for the fertility health screening.**

STUDY PROCEDURES AND VISIT SCHEDULE

Participants are randomly assigned to receive fertility health screening, fertility awareness tools or no intervention. Randomisation means assigning you to one of 3 groups by chance, like tossing a coin or rolling dice.

As you have been assigned to the fertility health screening group, you will need to make 3 visits to SGH or KKH, based on where you prefer to be seen. At the first visit, you will register at the clinic so that the Anti-Mullerian Hormone (AMH) test and semen analysis can be ordered. In the same visit, 3ml (about ½ teaspoon) of blood will be taken from the female partner for the AMH test. AMH is a hormone secreted by cells in developing egg sacs, so the levels of AMH can give an indication of your ovarian reserve.

For the male partner, an appointment will be made for the semen sample to be collected another day. This is difficult to do at the same visit as the sample has to be produced after sexual abstinence for 3-5 days and analysed fresh.

When the AMH and semen analysis results are out, the research coordinator will arrange an appointment with you and your spouse for another consultation with the gynaecologist and a reproductive counselling session with a nurse. It is important that both of you attend this consultation together.

The fertility health screening (AMH test and semen analysis) performed in this study aims to raise participants' awareness and understanding of their fertility health. It is not a complete fertility health screening and would not fully reflect the fertility status of you and your spouse.

Schedule of visits and procedures:
Visit 1 (Week 1): Registration and blood taking (wife)
Visit 2 (Week 2): Semen collection (husband)
Final Visit (Week 3): Consultation and reproductive counselling (both)

Your records will be checked after two and three years for any pregnancy related updates (i.e. birth).

Any human biological material obtained during the course of this study will be stored in Singapore and analyzed only for the purposes of this study for a period not exceeding 6 months, and will be destroyed after completion of the study.

The human biological material collected will not be used in restricted human biomedical research involving human-animal combinations in accordance to the Human Biomedical Research Act 2015 of Singapore (HBRA).

Any individually-identifiable data obtained during the course of this study will be stored and used only for the purposes of this study. These data will not be used for future research.

YOUR RESPONSIBILITIES IN THIS STUDY

As part of your participation in this study, you should:

- Undergo the study procedures as instructed and follow the advice given to you by the study team.
- Keep your study appointments. If it is necessary to miss an appointment, please contact the study staff to reschedule as soon as you know you will miss the appointment.
- Be prepared to visit the hospital up to 3 times and undergo all the procedures that are outlined above.

Chan SL, *et al. BMJ Open* 2022; 12:e051710. doi: 10.1136/bmjopen-2021-051710

WHAT IS NOT STANDARD CARE OR EXPERIMENTAL IN THIS STUDY

The study is being conducted because fertility health screening and reproductive counselling is not yet proven to be a standard intervention in couples without known fertility issues. We hope that your participation will help us to determine whether fertility health screening has any effect on childbearing decisions compared to no intervention or fertility awareness tools.

POSSIBLE RISKS, DISCOMFORTS AND INCONVENIENCES

There may be mild pain and bruising for the female partner from blood sampling, and inconvenience for the male partner from having to produce a semen sample in the clinic. As with any screening test, there could be a small chance of inaccurate results, which could lead to you experiencing unnecessary anxiety and treatments (if falsely positive) or having a false sense of security (if falsely negative). Therefore, the limitations of the tests will be emphasised and you will be advised accordingly by the attending gynaecologist.

POTENTIAL BENEFITS

If you participate in this study you will get information on your fertility status to make more informed childbearing decisions. However, the fertility health screening provided is not meant to be a full fertility evaluation and cannot check for all conditions that may affect fertility.

ALTERNATIVES

The study is being conducted because fertility health screening and reproductive counselling is not yet proven to be a standard intervention in couples without known fertility issues. We hope that your participation will help us to determine whether fertility health screening has any effect on childbearing decisions compared to no intervention or fertility awareness tools.
If you choose not to take part in this study, the alternative is to have what is considered standard care.

COSTS OF PARTICIPATION

If you take part in this study, the fertility health screening (AMH, semen analysis, consultation and counselling) will be performed at no charge to you.

You will be reimbursed $50 for your time, effort and transportation costs per couple per visit. In total, you and your spouse will be reimbursed $150 for all 3 visits.

In the event that you and your spouse wish to seek further medical follow-ups which are beyond the scope of this study (e.g. further consultations, endometriosis screening, diagnosis or treatments), you may wish to consult your preferred healthcare provider. These additional expenses are not covered under this study.

INCIDENTAL FINDINGS

In the case of an “incidental finding” (i.e. any abnormality that we did not expect to see in this study or unrelated to the purpose of this study), we will not re-identify and give you any results from the research.

PARTICIPANT’S RIGHTS

Your participation in this study is entirely voluntary. Your questions will be answered clearly and to your satisfaction.

In the event of any new information becoming available that may be relevant to your willingness to continue in this study, you (or your legal representative, if relevant) will be informed in a timely manner by the Principal Investigator or his/her representative and will be contacted for further consent if required.

The human biological material collected for the study will be deemed to be given to SGH and KKH. You give up your rights to the human biological material and any intellectual property rights that may be derived from the use of the human biological material.

By signing and participating in the study, you do not waive any of your legal rights to revoke your consent and withdraw from the study at any time.

WITHDRAWAL FROM STUDY

You are free to withdraw your consent and discontinue your participation at any time without prejudice to you or effect on your medical care. If you decide to stop taking part in this study, you should tell the Principal Investigator.

However, the data that have been collected until the time of your withdrawal will be kept and analysed. The reason is to enable a complete and comprehensive evaluation of the study.

The human biological material collected for the study will be deemed to be given to SGH and KKH and will not be returned to you. However, you retain your right to ask the Principal Investigator to discard or destroy any remaining samples if they have not been anonymised/ the human biological sample(s) is individually-identifiable and has not been used for the research or it has been used for research but it is practicable to discontinue further use of the human biological sample(s) for the research.

Your doctor, the Principal Investigator and/or the Sponsor of this study may stop your participation in the study at any time for one or more of the following reasons:

- Failure to follow the instructions of the Principal Investigator and/or study staff.
- The Principal Investigator decides that continuing your participation could be harmful.
- The study is cancelled.

RESEARCH RELATED INJURY AND COMPENSATION

If you follow the directions of the Principal Investigator of this research study and you are injured due to the research procedure given under the plan for the research study, our institution will provide you with the appropriate medical treatment.

Payment for management of the normally expected consequences of your treatment will not be provided by the SGH or KKH.

You still have all your legal rights. Nothing said here about treatment or compensation in any way alters your right to recover damages where you can prove negligence.

CONFIDENTIALITY OF STUDY AND MEDICAL RECORDS

Your participation in this study will involve the collection of Personal Data. Personal Data collected for this study will be kept confidential and used only for the purpose of the study in line with applicable laws and regulations. Only your Investigator(s) will have access to the confidential information being collected.

However, Regulatory Agencies, SingHealth Centralised Institutional Review Board and

Ministry of Health may be granted direct access to your original medical records to check study procedures and data, if necessary. None of your information will be made public.

By signing the Consent Form, you consent to (i) the collection, access to, use and storage of your Personal Data by SGH and KKH, and (ii) the disclosure of such Personal Data to our authorised service providers and relevant third parties.

"Personal Data" means data about you which makes you identifiable (i) from such data or (ii) from that data and other information which an organisation has or likely to have access. Examples of personal data include medical conditions, medications, investigations and treatment history.

Research arising in the future, based on this "Personal Data", will be subject to review by the relevant institutional review board.

Data collected and entered into the Data Collection Form(s) are the property of SGH and KKH. In the event of any publication regarding this study, your identity will remain confidential.

By participating in this research study, you are confirming that you have read, understood and consent to the SingHealth Data Protection Policy, the full version of which is available at www.singhealth.com.sg/pdpa.

WHO TO CONTACT IF YOU HAVE QUESTIONS REGARDING THE STUDY

If you have questions about this research study or in the case of any injuries during the course of this study, you may contact the Principal Investigator A/Prof Yu Su Ling (6576 7743) or the Site Principal Investigator Dr Chua Ka Hee (9822 7616).

WHO HAS REVIEWED THE STUDY

This study has been reviewed by the SingHealth Centralised Institutional Review Board for ethics approval.

If you have questions about your rights as a participant, you can call the SingHealth Centralised Institutional Review Board at 6323 7515 during office hours (8:30 am to 5:30pm).

If you have any feedback about this research study, you may contact the Principal Investigator or the SingHealth Centralised Institutional Review Board.

CONSENT FORM

Details of Research Study

Protocol Title:

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Department of Reproductive Medicine
KK Women's and Children's Hospital (KKH)
100 Bukit Timah Road
Singapore 229899
Tel: 9822 7616

I agree to participate in the research study as described and on the terms set out in the Participant Information Sheet.

I have fully discussed and understood the purpose and procedures of this study. I have been given the Participant Information Sheet and the opportunity to ask questions about this study and have received satisfactory answers and information.

I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reasons and without my medical care being affected.

By participating in this research study, I confirm that I have read, understood and consent to the SingHealth Data Protection Policy.

_____	_____	_____
Name of participant	Signature/Thumbprint (Right / Left)	Date of signing

To be completed by parent / legal guardian / legal representative, where applicable

I hereby give consent for the above participant to participate in the proposed research study. The nature, risks and benefits of the study have been explained clearly to me and I fully understand them.

I confirm that I have read, understood and consent to the SingHealth Data Protection Policy.

_____	_____	_____
Name of participant's parent/ legal guardian/ legal representative	Signature/ Thumbprint (Right / Left)	Date of signing

To be completed by translator, if required

The study has been explained to the participant/ legal representative in

_____by _____.
Language Name of translator

To be completed by witness, where applicable

I, the undersigned, certify that:

- I am 21 years of age or older.
- To the best of my knowledge, the participant or the participant's legal representative signing this informed consent form had the study fully explained in a language understood by him/ her and clearly understands the nature, risks and benefits of his/ her participation in the study.
- I have taken reasonable steps to ascertain the identity of the participant or the participant's legal representative giving the consent.
- I have taken steps to ascertain that the consent has been given voluntarily without any coercion or intimidation.

Witnessed by: _____ _____
Name of witness Date of signing

_____
Signature of witness

1. An impartial witness (who is 21 years of age or older, has mental capacity, who is independent of the research study, and cannot be unfairly influenced by people involved with the research study) should be present during the entire informed consent discussion if a participant or the participant's legal representative is unable to read, and/or sign and date on the consent form (i.e. using the participant or legal representative thumbprint). After the written consent form and any written information to be provided to participant, is read and explained to the participant or the participant's legal representative, and after the participant or the participant's legal representative has orally consented to the participant's participation in the study and, if capable of doing so, has signed and personally dated the consent form, the witness should sign and personally date the consent form. This is applicable for Clinical Trials regulated by HSA and Human Biomedical Research under HBRA.

2. For HBRA studies, the witness may be a member of the team carrying out the research only if a participant or the participant's legal representative is able to read, sign and date on the consent form.

Investigator's Statement

I, the undersigned, certify to the best of my knowledge that the participant/ participant's legal representative signing this consent form had the study fully explained and clearly understands the nature, risks and benefits of his/ her/ his ward's/ her ward's participation in the study.

_____	_____	_____
Name of Investigator/ Person obtaining consent	Signature	Date